

Appln. No.: 10/521,994  
Amendment Dated September 28, 2007  
Reply to Office Action of July 2, 2007

RCHP-132US

**Remarks/Arguments:**

Claims 1-40 are pending in the application. Applicants note that the Office Action Summary is stated to be responsive to the communication filed on 19 January 2005, but further note that the most recent filing was a preliminary amendment submitted by FAX on March 13, 2007. Applicants presume that the Office Action is directed to the claims set forth in that amendment.

**35 U.S.C. § 112**

Claims 16 and 31 are rejected under 35 U.S.C. § 112, 2nd paragraph as being indefinite. In claim 16, the terms "less prone" and "a polyurethane" are considered indefinite. Claim 16 is amended herewith to clarify that the lipid-modified polyurethane exhibits less oxidative degradation than an analogous polyurethane lacking a lipid substituent, under the same testing conditions. Support for the amendment may be found in the published application at paragraphs [0027], [0069], [0070], [0164], and Figs. 15 and 16.

In claim 31, use of the term "substantial" is considered indefinite, and the claim has now been amended to delete this term. Applicants submit that the 35 U.S.C. § 112 rejections have been overcome, and request their withdrawal.

**Double Patenting**

Claims 1-10, 17-23, 31-32 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting over claims 1, 9-20 and 27-29 of copending Application No. 11/233,149. Because the final scope of claims in the 11/233,149 application has not been determined, Applicants will defer consideration of double patenting until a suitable set of claims is allowed in that application.

**35 U.S.C. § 102**

Claims 1, 11-19, 31, 35 and 36 are rejected under 35 U.S.C. § 102(b) as anticipated by US 6,320,011 ("Levy"). The examiner bases the rejection on a contention that Levy teaches a modified polyurethane having a lipid substituent pendant from at least one urethane nitrogen and/or carbon atom. This contention is in error. Levy does not teach a lipid substituent, but rather a geminal bisphosphonate substituent, pendant from a polyurethane. As is seen in column 3 at lines 45-49 of Levy, and elsewhere in that patent, a geminal bisphosphonate group is a carbon atom with two PO<sub>3</sub>H<sub>2</sub> groups attached to it. In contrast, the term "lipid" is "An inclusive term for fats and fat-derived materials." See Hawley's Condensed Chemical Dictionary, 14<sup>th</sup> Edition, ©2001 by John Wiley & Sons Inc., New York. Applicants are unable to find any reference at all by Levy to lipids in any capacity, much less as substituents on a polyurethane.

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Accordingly, not all of the claim elements have been taught and the rejection should be withdrawn.

Claims 1 and 2 are rejected under 35 U.S.C. § 102(b) as anticipated by US 4,745,136 ("Thomas"). The rejection is based on an assertion that Thomas teaches a modified polyurethane having cholesterol pendant from at least one carbon atom thereof. The examiner points to Col. 2 lines 23-30 and 45-52 to support this contention, but those passages do not disclose cholesterol (or any lipid substituent) pendant from at least one urethane nitrogen and/or at least one carbon atom of a polyurethane as presently claimed. Rather, those passages (and in fact all of Thomas) teach a polymer formed entirely from an ethylenically unsaturated steroid derivative, for example an ester of methacrylic acid with a cholesterol-containing alcohol such as shown in Col. 8, lines 47-53 of Thomas. This polymer is not a polyurethane.

Page 903 of Hawley's Condensed Chemical Dictionary (cited above) defines "polyurethane" as "A thermoplastic polymer (which can be made by thermosetting) produced by the condensation reaction of a polyisocyanate and a hydroxyl-containing material, e.g., a polyol derived from propylene oxide or trichlorobutylene oxide." Such a reaction product is indeed described by Thomas, but it does not have any cholesterol or other lipid substituents on it as presently claimed. The cholesterol-containing polymer is merely "dissolved or dispersed" in the polyol, and the polyol reacts with the polyisocyanate to form the polyurethane. (See Column 2, lines 23-30). Thomas does not teach reaction of the cholesterol-containing polymer with the polyisocyanate, the polyol, or the polyisocyanate-polyol reaction product. Thus, Thomas' polyurethane is merely present in admixture with the polymer that contains the cholesterol groups. Since cholesterol is not pendant from the polyurethane, not all of the claim elements have been taught and the rejection should be withdrawn.

### 35 U.S.C. § 103

Claims 2-3, 5-9, 20, 21, 23, 32-34 and 37 are rejected under 35 U.S.C. § 103(a) as unpatentable over Levy in view of U.S. Appln. No. 2002/0045263 ("Leong"). The examiner states that Leong teaches polymers having urethane and phosphate linkages. However, although Leong teaches phosphate linkages, he does not teach phosphonate linkages, nor indeed phosphonate groups at all. And although he teaches the presence of urethane groups, he does not teach a polyurethane that contains phosphonate groups (or even phosphate groups). Rather, the inventive polymer taught by Leong is a polyphosphate, i.e., a polymer with repeating phosphate linkages in the main chain. The polyphosphate may also contain some urethane (not polyurethane) groups. (See Abstract, [0055], and [0056]). The term

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"urethane" is defined on page 1154 of Hawley's Condensed Chemical Dictionary (cited above) as the compound ethyl carbamate, which has the formula  $H_2N-CO-OC_2H_5$ . Thomas' only mention of polyurethanes (previously defined herein) is at [0308], where he says that they may be blended with his inventive polyphosphates.


The examiner bases his finding of obviousness on a premise that Leong teaches the value of including cholesterol groups in bio-implants that also contain phosphonate groups. But as explained above, this premise is false. Leong never combines cholesterol with phosphonate groups, only with phosphate groups. Thus a *prima facie* case of obviousness has not been presented. Accordingly, the rejection should be withdrawn.

Claims 38-40 are rejected under 35 U.S.C. § 103(a) as unpatentable over Levy in view of US 4,960,423 ("Smith"). Smith is relied upon to teach the attachment of endothelial cells to bio-implants, but Smith does not overcome the deficiencies of Levy with respect to appending a lipid from a polyurethane, as discussed hereinabove. Thus not all of the claim elements are taught by the Levy in view of Smith, and a *prima facie* case of obviousness has not been presented. Therefore, the rejection should be withdrawn.

#### Conclusion

Applicants thank the examiner for indicating that claims 24-30 contain allowable subject matter. In view of the remarks presented above, Applicants submit that the need to cast them in independent form to obtain allowance has now been obviated. Applicants respectfully request reconsideration and allowance of all of the claims, and invite the examiner to contact their undersigned representative Frank Tise if it appears that this may expedite examination.

Respectfully submitted,

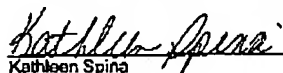
  
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CAR/FPT/ks

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The Director is hereby authorized to charge or credit Deposit Account No. 18-0350 for any additional fees, or any underpayment or credit for overpayment in connection herewith.

I hereby certify that this correspondence is being facsimile transmitted 571-273-8300 to the USPTO or deposited with the United States addressed to: Mail Stop Amendment Commissioner for Patents, on: September 28, 2007

  
Kathleen Spina